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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/705,403  | 11/10/2003  | Satoshi Mizutani     | 20050/0200484-US0   | 4411             |
| 7278  | 7590        | 08/22/2005           | EXAMINER            |                  |
| DARBY & DARBY P.C.<br>P. O. BOX 5257<br>NEW YORK, NY 10150-5257 |             |                      | REICHLE, KARIN M    |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |

3761

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/705,403 | <b>Applicant(s)</b><br>MIZUTANI ET AL. |  |
|                              | <b>Examiner</b><br>Karin M. Reichle  | <b>Art Unit</b><br>3761                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 July 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 7-10, 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 6 and 11-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. PCT/JP02/04891.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/04, 6/04, 7/04, 8/05</u> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of the layer configuration species of Figures 1-16, the minisheet configuration species of Figure 9A, the package configuration species of Figure 22B and the attachment configuration species of Figures 10A in the reply filed on 7-7-05 is acknowledged.

2. Claims 2-4, 7-10 and 15-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7-7-05.

Claims 2-3, and thereby claims 15-16, and claims 4, 7-10 are withdrawn either because the Figures of the elected species do not show the claimed structure, e.g. Figures 1-16, 9A, 10A and 22B do not show a convex area with a triangular longitudinal cross section as claimed in claim 8, i.e. the elected species has a lateral cross section of triangular shape, or it is unclear whether such read on the elected species or not, e.g. in claim 3, what "sleeve portion"? No sleeve portion is claimed in claim 1.

### *Specification*

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

For Example:

### *Drawings*

4. The drawings are objected to because Figures 25-27 should be labeled PRIOR ART. Cross-sectional lines, e.g. X-X in Figure 1, should be denoted by Roman or Arabic numerals not letters. Figures 10(A)-(D) are inconsistent with the description thereof, i.e. they are cross-sections but not described as such. In Figures 2 and 3(A)-(B), the numeral 6 should not be underlined. This also applies to 61a in Figure 1, 62a in Figures 2 and 3(A)-(B), and 62 in Figures 10(A)-(D). In Figure 3(A), 19B should not be shown, i.e. see direction of view along line X-X in Figure 1. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

*Description*

5. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: the abstract.

6. The abstract of the disclosure is objected to because the abstract should be limited to between 50 and 150 words in length. Also terminology which can be inferred, e.g. "Disclosed is", should be avoided. Correction is required. See MPEP § 608.01(b).

7. The disclosure is objected to because of the following informalities: The specification is replete with informalities. For example: 1) On page 3, line 10, "Disclosure of the invention" should be --Summary of the Invention--. 2) The Summary of the Invention section, i.e. a description of the claimed invention, and the invention of the claims is not commensurate in scope, see MPEP 608.01(d). 3) On page 19, line 20, "(A-C)" should be --(A)-(C)--. This also applies to similar language with respect to Figures 10, 13, 17 and 22-24. 4) On page 21, line 25, "3" should be --3(A)-(B)--. 5) On page 23, line 9, what sleeve and openings thereof of the long convex area? On page 23, lines 16-17, what are the sleeve portions? The edges of minisheet 14 or something else? 6) On page 44, line 21, "17" should be --17(A)-(B)--. 7) On page 27, line 11, "9" should be --9(A)-(C)--. 8) The description on page 28, lines 4-7 is unclear, i.e. the finger is exposed in Figure 9(B) contrary to the description. This also applies to page 28, lines 8-11, i.e. Figure 9(C) does not prevent exposure in the same manner as described. 9) On page 29, line

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4, “form” should be --from--. On page 29, lines 23 et seq, the terminology “longitudinal cross sectional” and “in the lateral direction” appear to be inconsistent, i.e. the cross section is either in the longitudinal or lateral direction, not both. 10) On page 41, line 19, “13” should be --13(A)-(B)--. 11) What is 41 in Figures 22(A)-(B)? 12) “Best Mode of Carrying Out the Invention” on page 21, line 14 should be --Detailed Description of the Invention--. The specification should be carefully reviewed and revised, as necessary, to overcome all the informalities. Applicant is thanked in advance for the cooperation in placing the specification in proper form.

Appropriate correction is required.

### ***Claim Objections***

8. Claims 1, 5-6 and 11-14 are objected to because of the following informalities: In claim 1, lines 4 and 11, “water...non-permeable” should be deleted. On line 5, “opposite side” should be --side opposite--. On line 11, “at” should be --toward--. On line 12, before “facing”, -for-- should be inserted. On line 17, “side sheet” should be --sheet side--. In claims 5-6 and 11-13, line 1, “an” should be --The--. The preamble of claim 14, a claim dependent from claim 1, is inconsistent with that of claim 1. In claim 5, line 3, “at” should be --toward-- and “the ...forming” should be deleted. On line 4, after “opening”, --formed-- should be inserted. In claim 6, lines 2-3, “formed by bending” should be --of--. In claim 11, lines 1-2, “a...is” should be deleted. In claim 14, lines 3-4 should be deleted and on line 2, “the” should be --an individual--. Appropriate correction is required.

***Claim Language Interpretation***

9. The claim terminology is interpreted in light of the specific definitions on page 6, lines 8-9 and page 8, lines 9-13. Any other claim language not specifically defined has been interpreted in view of the usual and common meaning of such, i.e. the dictionary definition. It is noted that the terminology “mini” in claim 5 has not been claimed with respect to any other structure, i.e. mini compared to what, and thereby is considered relative absent specific dimensions thereof.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-2, 6 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Gann PCT ‘270.

Claims 1, 6 and 14: See Claim Language Interpretation section supra and Gann at Figures, especially 1 and 34-38, page 10, lines 5-18, page 12, first two full paragraphs, the paragraph bridging pages 12-13, page 13, first full paragraph, page 20, fourth full paragraph, page 23, second full paragraph, page 26, first full paragraph, page 37, first full paragraph, page 38, second-fourth full paragraphs, page 39 and page 40 first full paragraph, i.e. the interlabial pad is 20, the main sheet body is 22 which includes an absorbent body 42 enclosed by a surface sheet, 40 or 42 or a portion of 40 inserted in the labia, and a back side sheet, the other of 42 or 40

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or the remainder of sheet 40, see page 26, first full paragraph again, and a convex area, see Figures 34-35 for example, and the subsheet body is 24 which includes a surface sheet 70, a back side sheet 72 and an absorbent core 74. The pad 20 can be individually packed in a container, see cited portions supra.

Claims 11-13: These claims recite functions, properties or capabilities of the structure set forth in claim 1. If not already taught by the Gann, see the portions cited supra, the Gann reference at the very least teaches such structure of claim 1. Therefore there is sufficient factual evidence for one to conclude that such same structure of Gann also inherently includes such claimed functions, properties and capabilities, see MPEP 2112.01. It is noted that claim 11 does not further require any further structure, i.e. a napkin, and the Gann device is a sanitary napkin coexisting labial pad, as best understood.

### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 50 is rejected under 35 U.S.C. 103(a) as obvious over Gann '270 in view of Wierlacher '096.

Applicant further claims a minisheet piece fixed to the back side sheet of the subsheets to define a finger insertion opening therebetween. The Gann reference teaches various fit assist mechanisms in the portions cited supra but does not teach a sheet as claimed. However, see



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Wierlacher '096 at page 17, line 30-page 21, line 3, i.e. fit assist mechanisms can be one or more strings or strips, i.e. sheet bonded to outermost sheet to define an opening therebetween, e.g. a finger loop, as claimed or a series of finger loops intended to allow insertion of at least one finger. Therefore, to make the fit assistance mechanism of Gann a minisheet as taught by Wierlacher would be obvious, see *In re Siebentritt*, 54 CCPA 1083, i.e. two equivalents are interchangeable for their desired function, express suggestion of desirability of substitution not needed to render such substitution obvious, i.e. in the instant case the desired function is fit assistance of a pad adjacent the pudendal region.

### ***Double Patenting***

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1, 5-6 and 11-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 8, and 10-14 of copending Application No. 10/705,812. Although the conflicting claims are not identical, they are not patentably distinct from each other because since both applications have the same effective filing date, the one-way *In re Vogel* test applies, i.e. are the claims of the instant

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application obvious in view of the claims of the copending application? The answer is yes. The claims of the instant application are both 1) broader than the claims of the copending application, i.e. do not include a bend inducing line, or 2) narrower than the claims of the copending application, e.g. all the claims include a formed convex area. With respect to 1), once an applicant has received a patent for a species or more specific embodiment he/she is not entitled to a patent for the generic or broader invention without maintaining common ownership and ensuring that the term of the latter application patent will expire at the end of the original term of the original term of the earlier issued patent. This is because the more specific anticipates the broader. See *In re Goodman*, supra. With respect to 2), it would be obvious to one of ordinary skill in the art to employ sheet bodies without a formed convex area since it has been held the omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art, *In re Karlson*, 136 USPQ 184.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art to McDevitt also shows two sheet bodies of the size capable of interlabial insertion. It is noted that the 4-8-04 IDS sets forth that there are a total of 2 pages. However, only the first page, i.e. Sheet 1 of 2, is of record.


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17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936.

The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Karin M. Reichle  
Primary Examiner  
Art Unit 3761

KMR  
August 4, 2005